



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,762	12/28/2000	Kazuyuki Yanase	114474-14-FESI00002US	5214
38492 7590 02/12/2010 WILLKIE FARR & GALLAGHER LLP INTELLECTUAL PROPERTY LEGAL ASSISTANTS 787 SEVENTH AVE NEW YORK, NY 10019-6099				
EXAMINER				
HAMO, PATRICK				
ART UNIT		PAPER NUMBER		
3746				
MAIL DATE		DELIVERY MODE		
02/12/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/720,762

Applicant(s)

YANASE ET AL.

Examiner

PATRICK HAMO

Art Unit

3746

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 6-9, 11, 13, 19-22 and 33-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 6-9, 11, 13, 19-22 and 33-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-85/86)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 30, 2009 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 6-9, 11, 13, 19-22, and 33-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In independent claims 1, 9 and 33, applicant claims that the restriction "has an inner diameter with a ratio of 0.8 or more and less than 1.0 to a diameter of the gasket." This is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

possession of the claimed invention. The original disclosure discusses a gasket diameter of 30-35mm and a restriction with depths between 0.05 and 1 mm in the broadest claimed range. There is no discussion of the ratio, although the ratios may be inferred from this information. Even so, the smallest ratio of restriction diameter to gasket diameter that can be gleaned from this information is 28:30 (taking the smallest disclosed gasket diameter of 30mm and largest disclosed restriction depth of 1mm, for a smallest restriction diameter of 28mm) or about 0.9333. There is no support for the claimed ratio of 0.8 as a lower end.

Furthermore, in independent claims 1 and 9, the limitation that "only the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with polyethylene fluoride resin" is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original disclosure discusses a polyethylene fluoride resin on "the peripheral side surface that is in contact with the inner surface of the syringe barrel and/or a bottom surface that is in contact with liquid." In view of this disclosure, the limitation above is narrower than applicant's original supporting disclosure. See *Gentry Gallery*, 134 F.3d at 1479; see also *Tronzo v. Biomet*, 156 F.3d at 1158-59. MPEP 2163(1)(B).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 6-9 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al., 6,080,136 in view of Ivey, 5,976,299 further in view of Sudo et al., 5,009,646, and further in view of Akaiki et al., 5,061,247.

Trull, in figure 6, discloses a syringe gasket (70) wherein a peripheral side surface (80) of the gasket is in contact with an inner surface of the syringe barrel (60). A restriction and a tapered slant with a first and second plunger diameter (see fig. 6) is provided, and a periphery of a bottom surface of the gasket that is not in contact with the liquid is formed into a tapered slant (see fig. 6).

Trull does not teach that the barrel is composed of a polyethylene fiber or one or both of the peripheral side surfaces that is in contact with an inner surface of the syringe barrel and a surface of the gasket that is in contact with the liquid is laminated with polyethylene fluoride resin.

However, Ivey teaches the use polyethylene film, composed of polyethylene fibers (col. 5, lines 1-4) to make sterilizable receptacles for medical use, including syringes (col. 1, lines 13-24). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to have made the barrel of Trull out of polyolefin fibers to make the syringe sterilizable and therefore reusable.

Furthermore, Sudo teaches a syringe gasket (2) coated (3) with a thermoplastic resin such as polyethylene (col. 2 lines 10-24) to provide sealing and lubrication while

preventing contamination from liquid lubricants (col. 1 lines 48-55). In regard to the claimed limitation that the restriction has an inner diameter ratio of 0.8 or more and less than 1.0 of a diameter of the gasket, this constitutes a change in proportion of the gap 6 taught by Sudo. In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Trull et al. gasket by using a gasket material of polyethylene, as taught by Sudo et al., in order to eliminate the need for a lubricant and serve as a protective sealant coating for the gasket.

With respect to the fact that Sudo teaches the coating for more than just the peripheral side surface, namely the top surface in contact with the pumped liquid as a sealant, it is brought to applicant's attention that the bottom surface is not coated. This surface is not coated because coating it with a lubricant or sealant is not required. The coating has two functions, namely to lubricate and to seal. For the side surface, both of these functions are utilized. For the top portion, only the function of sealant is being utilized. In the present application, the coating and its function (sealing) are removed from the top surface. This does not add patentable weight because it would have been

obvious to omit the coating where the function attributed to the coating is not desired or required. See MPEP §2144.04(2)(a).

Furthermore, Trull does not teach that the first and second diameter of the tapered slant have a difference between about .5mm and about 5mm or that the gasket's inner diameter, its height, its first diameter, or its second diameter. With respect to the specified gasket dimensions in the claims 3, 6-8, 19, 21,22, and 24-28, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 CCPA (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D.C. 324, 135 F.2d 11, 57 USPQ 136.

With respect to claim 9, a second tapered (see examiner's marked up Figure 6 in the office action dated October 2, 2006) slant is formed between the peripheral side surface of the gasket (70) that is in contact with an inner surface of the syringe barrel (60) and the restriction (see examiner's marked up Figure 6). The gasket tightly closing the liquid is an obvious requirement for the syringe to pump fluid properly. A recitation with respect to the material intended to be worked upon by a claimed apparatus, in this case a contrast medium, does not impose any structural limitations upon the claimed apparatus, which differentiates it from the prior art apparatus satisfying the structural limitations of the claims, as is the case here.

The above teach all of the limitations substantially as claimed except for the following: the gasket being made integrally of a material with JIS hardness of 55 to 60.

However, Akaike et al., in column 5 lines 58-59, disclose, that a hardness of JIS of 20-85 is optimal for gaskets applied to syringe devices. This general range covers the applicants claimed range. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify references as applied to claims 1 and 9 above with a gasket material of 20-85 JIS hardness in order to achieve optimum gasket functionality within a syringe device. With respect to the specific range of JIS hardness 55 to 60, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 CCPA (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D.C. 324, 135 F.2d 11, 57 USPQ 136. Other than the range being preferred for presumably general optimum device function, the applicant has provided no criticality or unexpected or non-obvious advantage over choosing one this particular range. The coating taught by the prior art is integral in that the coating and the plunger coated form an integral plunger assembly.

Claims 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1 and 9 above, and further in view of Higashikawa, 5,830,193.

The references as applied to claim 1 above teach all of the limitations substantially as claimed except for the following: that the syringe includes a luer lock.

However, Higashikawa in Figure 1a-1c, 7a, and 7b, teaches that luer lock mechanisms (37, 30, 22) have been especially common in medical syringes (21) for mounting needles (32) - see column 7 line 49.

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the references as applied to claims 1 and 9 above by incorporating the luer locking mechanism, as taught by Higashikawa, in order to allow for needle mounting.

Claims 33-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 in view of Vacca, 5,531,255.

The references as applied to claim 1 above teach all of the limitations substantially as claimed except for the following: that only wherein the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with silicon.

However, Vacca teaches that adding lubricant to a syringe improves its performance and that silicon is a suitable lubricant (col. 3, ll. 14-18).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the references if claim 1 above with the silicon lubrication of Vacca in order to improve the performance of the syringe.

Response to Arguments

Applicant's arguments filed December 30, 2009 have been fully considered but they are not persuasive.

Examiner respectfully disagrees with applicant's contention that Sudo teaches away from the claimed limitation and therefore cannot read on the claims. Examiner, in the prior action and above, acknowledges that Sudo teaches laminating more than the portion of the syringe claimed. However, as stated above and previously, it would have been obvious to omit the lamination of a portion of the syringe *and* its function. To repeat, with respect to the fact that Sudo teaches the coating for more than just the peripheral side surface, namely the top surface in contact with the pumped liquid as a sealant, it is brought to applicant's attention that the bottom surface is not coated. This surface is not coated because coating it with a lubricant or sealant is not required. The coating has two functions, namely to lubricate and to seal. For the side surface, both of these functions are utilized. For the top portion, only the function of sealant is being utilized. In the present application, the coating and its function (sealing) are removed from the top surface. This does not add patentable weight because it would have been obvious to omit the coating where the function attributed to the coating is not desired or required. See MPEP §2144.04(2)(a). The examiner respectfully submits that the reference was considered as whole, including the portions that applicant argues lead away from the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICK HAMO whose telephone number is (571)272-3492. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Devon Kramer can be reached on 571-272-7118. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Devon C Kramer/
Supervisory Patent Examiner, Art
Unit 3746

/Patrick Hamo/
Patent Examiner, AU 3746